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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,176	01/24/2005	Yuuichi Murayama	101551.55779US	7682
23911 7590 10/12/2007 CROWELL & MORING LLP INTELLECTUAL PROPERTY GROUP P.O. BOX 14300 WASHINGTON, DC 20044-4300			EXAMINER JAVANMARD, SAHAR	
			ART UNIT 4133	PAPER NUMBER
			MAIL DATE 10/12/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/520,176

Applicant(s)

MURAYAMA ET AL.

Examiner

SAHAR JAVANMARD

Art Unit

1609

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 13-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 13-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 05 January 2005.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

The Office Action is in response to the 371 of PCT/JP02/08209 filed January 5, 2005. Amended claims 1-9 and 13-19 are being examined on the merits herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-19 are rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling for the treatment of suppressing the proliferation of abnormal prion proteins, does not reasonably provide enablement for the prevention of suppressing the proliferation of abnormal prion proteins as recited in these claims.

The instant claims are drawn to a suppressive agent and a method for the prevention of suppressing the proliferation of abnormal prion proteins. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims;

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(6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention:

The instant invention pertains to a method for the prevention of suppressing the proliferation of abnormal prion proteins.

The state of the prior art:

The skilled artisan would view that the prevention of prion diseases by suppressing the proliferation of abnormal prion proteins totally, absolutely, or permanently, is highly unlikely, since one cannot guarantee that suppressing the proliferation of abnormal prion proteins will always be prevented.

The relative skill of those in the art:

The relative skill of those in the art is very high.

The predictability or lack thereof in the art:

The skilled artisan would view that the prevention of prion diseases by suppressing the proliferation of abnormal prion proteins, totally, absolutely, or permanently is highly unpredictable.

The amount of direction or guidance presented and the presence or absence of working examples:

In the instant case, no working examples are presented in the specification as filed showing how to prevent prion diseases by suppressing the proliferation of abnormal prion proteins totally, absolutely, or permanently. Note that lack of a working example, is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.

Genentech, Inc. v. Novo Nordisk, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the *Wands* factors, e.g., the amount of direction or guidance provided, absence of working examples, and the predictability of the art discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test the combination in the instant claims whether preventing prion diseases by suppressing the proliferation of abnormal prion proteins totally, absolutely, or permanently.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 13-15 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Richardson et al. (WO 96/21437).

Richardson teaches a method of remitting or attenuating the symptoms of abnormal movement disorders by administering a meal enriched with large neutral amino acids to patients suffering from these disorders (abstract, page 1, lines 1-3).

Richardson teaches a number of neurological disorders that are manifested by abnormal movements, including among many diseases, Creutzfeldt-Jacob disease (page 2, lines 22-33). Richardson further teaches that branched chain amino acids or aromatic acids are administered to alleviate abnormal movement disorders in particular isoleucine, leucine, and valine (page 10, lines 13-21; page 25, example 2; claims). Additionally, Richardson teaches that the branched amino acids can be administered in the form of various pharmaceutical preparations such as tablets, capsules, flavored bars, suspensions, and emulsions (page 41, lines 11-15), meeting the limitations of claims 1-9, 13-15, and 18.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 and 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richardson in view of Gordon (WO 00/64420).

Richardson is discussed above.

Richardson does not teach neurodegenerative diseases such as scrapie, bovine spongiform encephalitis, and Gertsmann-Straussler-Scheinker syndrome.

Gordon teaches that neurodegenerative disease Creutzfeldt-Jakob disease is characterized by the appearance and accumulation of a protein-resistant form of a prion protein in the central nervous system (page 1, lines 25-30) in addition to other neurodegenerative diseases including scrapie, bovine spongiform encephalitis, and Gertsmann-Straussler-Scheinker syndrome (page 23, lines 10-12).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have administered a meal enriched with large neutral amino acids to patients suffering from disorders such as Creutzfeldt-Jacob disease as taught by Richardson to also treat patients with the neurodegenerative diseases set forth by Gordon including Creutzfeldt-Jakob disease (mentioned by Richardson) as well as scrapie, bovine spongiform encephalitis, and Gertsmann-Straussler-Scheinker syndrome. The motivation is that all of these neurodegenerative diseases are characterized by the appearance and accumulation of a protein-resistant form of a prion protein in the central nervous system and it is reasonable to treat diseases that have similar characteristics with similar forms of treatment.

Conclusion

Claims 1-9 and 13-19 are not allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY STUCKER can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



JEFFREY STUCKER
SUPERVISORY PATENT EXAMINER